12/30/98

JUL - 1 1999

K984640

510 (k) Summary of Safety and Effectiveness

This 510 (k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92. This device is a Class II device per 21 CFR 864.9205, nonelectromagnetic blood and plasma warming device; henceforth referred to as the Thermal Angel™.

Submitter:

Estill Medical Technologies, Inc.
17440 N. Dallas Parkway,
Suite 100
Dallas, TX 75287

Contact:

Thomas L. Kistner, President
Phone: (972) 818-1872
Fax: (972) 818-4329

Date Prepared: December 30, 1998

Trade/Proprietary Name: Thermal Angel™ 200 Blood/Fluid Warmer

Classification Name: Warmer, blood, nonelectromagnetic

Predicate Devices: Augustine Medical Bair Hugger™ Blood/Fluid Warmer, Level 1 Technologies, Inc. Hotline™ Fluid Warmer, Baxter Thermacyl™ Blood/Fluid Warmer.

Description of device:

The Thermal Angel™ 200 Blood/Fluid Warmer consists of a single unit that is placed in-line between a standard IV drip set and a standard IV extension set. Thermal Angel™ is designed to warm blood, blood products and intravenous liquids at flow rates of up to and including 200 ml/min. Thermal Angel™ will deliver temperatures at 38°C. While the temperature will drop immediately after making major changes in flow rate, it will drop only a few degrees and return smoothly, and within seconds, to 38°C.

Thermal Angel's™ fluid path is sterile and the entire unit is disposable after use. Blood, blood products or intravenous fluids travel through stainless steel tubing which is surrounded by a heating blanket and heated by means of electrical resistance. The temperature of the device is accurately controlled by the device's electronics. The electrical requirements are designed in accordance with UL 2601 and CSA 601.

Statement of Intended Use:

The Thermal Angel™ 200 Blood/Fluid Warmer is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals

in clinical and field environments.

Comparison of the Technological Characteristics of the New Device and the Predicate Devices:

The Thermal Angel™ 200 Blood/Fluid Warmer is substantially equivalent to the Augustine Medical Bair Hugger™ Blood/Fluid Warmer (K973741), the Baxter Thermacyl™ Blood/Fluid Warmer (K770232) and the Level 1 Technologies, Inc. Hotline™ Fluid Warmer (K911383). A comparison of technological features are on the following page.

Discussion of Nonclinical Studies:

Studies will be conducted to evaluate the hemolytic effect of the new device prior to marketing. Percent hemolysis will be evaluated during flow, stop flow and highest flow rate possible conditions. Hemolysis must show to be none or not clinically significant before introduction into commerce.

Conclusion:

The Thermal Angel™ 200 Blood/Fluid Warmer has similar technological characteristics and the same intended use as devices currently on the market. Therefore, because of the similarities to the predicate devices, Estill Medical Technologies, Inc. believes this new device does not raise any new safety or effectiveness issues.

Comparison of Technological Features				
Features	**Thermal Angel 200**	**Bair Hugger Blood/Fluid Warmer**	**Baxter Thermacyl Blood/ Fluid Warmer**	**Level I Technologies, Inc. Hotline Fluid Warmer**
(k)#	Not yet assigned	K973741	K770232	K911383
Heating Method	Heating blanket covering stainless steel tubing; heated by electrical resistance	Metal plate heated by electrical resistance	Metal cylinder heated by electrical resistance	Cirulating water heated by regulated resistance heater
Temperature Control	DS1821S Temp Sensors	Thermocouples	Thermistors (2 inlet; 2 outlet)	Water temp is displayed
Alarm	Visual; LED indicators	Audio/Visual	Audio/Visual	Audible
Alarm Conditions	Illumination: Red fading to dim or no light = no power Green fading to dim or no light = decrease in heat. Safety switch turns off TA @ 41.0*C	Temperature @ 32.0*C; 43.0*C' 46.0*C	Temperature exceeds 42.0*C or thermisters differ by 5.0*C	Red "overtemperature" indicator illuminated alarm @ 41.0*C
Electronics	Microprocessor Control	PID Controlled	UL2601; CSA601	Proportional controller
Operation	12V Battery system			120V-AC
Flow	TK0-200 ml/min	0-500 ml/min	up to 500 ml/min	5.0-50 ml/min
Infusion Temp.	38*C	42.0*C Max	Up to 42.0*C	35.0*C-39.0*C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL -1 1999

Mr. Thomas L. Kistner
President
Estill Medical Technologies, Incorporated
17440 North Dallas Parkway
Dallas, Texas 75287

Re: K984640
Trade Name: Thermal Angel™
Regulatory Class: II
Product Code: BSB
Dated: April 5, 1999
Received: April 6, 1999

Dear Mr. Kistner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if Known): K984640

Device Name: Thermal Angel™

Indications for use: Thermal Angel™ is an in-line intravenous fluid and blood warmer. Thermal Angel™ is indicated for use whenever parenteral introduction of normothermic fluids are desired or indicated, whether in field or clinical settings.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

Susan Runner for PXC
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984640